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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/975,317	10/12/2001	Alan David Watson	WATS3001/REF/C	8178

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EXAMINER	
JONES, DAMERON LEVEST	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 07/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/975,317	WATSON ET AL.	
	Examiner	Art Unit	
	D. L. Jones	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *76-81,84-86,88-93 and 96* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *76-81, 84-86, 88-93, and 96* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

CLARIFICATION OF THE RECORD

1. The last office action mailed 12/28/05 is WITHDRAWN in light of the rejection set forth below.

2. The Examiner acknowledges receipt of the amendment filed 8/22/05 wherein claims 1-75, 82, 83, 87, 94, and 95 are canceled; claims 76, 77, 80, 84-86, 88, 90, 92, and 93 are amended; and claim 96 is added.

Notes: (1) In the amendment filed 8/22/05, the status of claims 88, 90, 92, and 93 is incorrect. The claims identifier should be 'currently amended', not 'new'.

(2) Claims 76-81, 84-86, 88-93, and 96 are pending.

3. The rejection under 35 U.S.C. 102(b) as being anticipated by Rocklage (US Patent No. 5,190,744) is WITHDRAWN because Applicant has amended/canceled the claims to overcome the previously cited prior art.

NEW GROUNDS OF REJECTION

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 76, 77, 79-81, 84-86, 88-93, and 96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rocklage (US Patent No. 5,190,744) in view of Rocklage (US Patent No. 4,889,931).

Rocklage '744 discloses a method of detecting myocardial ischemia in a subject comprising administering a contrast medium comprising a manganese complex and subjecting the subject to a fast MRI technique to detect abnormal blood flow (see abstract). Methods of fast MRI, as claimed, are disclosed in column 2 (lines 10-32). Manganese chelates are disclosed in column 4 (line 55) and claim 26 of the patent. The dosages are within the claimed dosages (column 5, lines 38-61). The methods of Rocklage '744 are for imaging myocardial ischemia (column 2, lines 33-38 and column 8, lines 17-57). In addition, Rocklage '744 discloses that various known chelating agents may be employed (column 4, lines 19-49). However, Rocklage '744 fails to specifically disclose the use of the same contrast agents as instantly claimed (e.g., manganese complexes, such as that in newly added claim 96), but does disclose the used of its contrast agents for cardiovascular system imaging.

Rocklage '931 discloses MRI contrast agents comprising manganese chelates which are highly stable chelating agents and thus are suitable for method of imaging (column 2, lines 1-40). In addition, the reference discloses that manganese is the preferred metal for such MRI complexes (column 3, lines 34-36). The contrast agents include manganese complexes of DPDP (column 4, lines 47-50). It should be noted that these chelates are the same as those of the instant invention (see column 3, formula I and columns 4-5, bridging paragraph).

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Rocklage '744 using the teachings of Rocklage '931 and generate a method of distinguishing viable myocardial tissue from necrotic (infracted) tissue in a subject as set forth in independent claim 96 because: (1) both references disclose the use of contrast agents for imaging the cardiovascular system; and (2) the chelating agents disclosed by Rocklage '931 encompass those of the instant invention. (3) Also, a skilled practitioner in the art would recognize that imaging the heart generates an image of the complete heart, so while the entire heart will be imaged, the intensity of the contrast agent absorb would vary depending upon the type of tissue (i.e., infracted and/or healthy) present. For example, the skilled practitioner would recognized that the properties of infarct and healthy tissue are different so, the outcome from administering a composition would differ such that both while both tissues would be imaged, one would be able to distinguished between the two based on the intensity of absorbed contrast agent. (4) In addition, a skilled practitioner in the art would recognize that since the compositions administered to the subject are the same, the properties of those compositions would be the same as well. Thus, if Applicant's contrast agent is capable of distinguishing between viable and necrotic myocardial tissue, the contrast agents of the prior art would also possess those properties. (5) Furthermore, it is noted that in Rocklage '744, it is disclosed that MRI using magnetic susceptibility contrast agents allows one to determine the existence and location of a perfusion deficit and detect the degree or severity, and if possible the onset

and duration, of abnormalities or variations in a quantifiable manner when a subject is administered a contrast agent (abstract; column 1, lines 7-12 and 26-55).

6. Claims 77, 78, and 96 are is rejected under 35 U.S.C. 103(a) as being unpatentable over Rocklage (US Patent No. 5,190,744) in view of Goldenberg (US Patent No. 5,632,968).

Rocklage '744 (also see discussion above) discloses that various varieties of echo planer imaging are suitable with their invention (column 2, lines 19-23), but fails to specifically disclose that the echo imaging is an inversion recovery echo imaging method.

Goldenberg disclose method of imaging cardiovascular lesion and teaches that inversion recovery is a well known and equivalent method of spin-echo MRI (column 13, lines 23-48).

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the method disclosed by Rocklage '744 and use inversion-recovery spin-echo MRI as the spin echo MRI procedure because it is well known in the art, as indicated by Goldenberg, that such technique is useful and an equivalent method of spin-echo MRI.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

D. L. Jones
Primary Examiner
Art Unit 1618

June 30, 2006